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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
EDWARDS, LAURA ESTELLE	
ART UNIT	PAPER NUMBER
1792	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/747,996	CHEN ET AL.	
	Examiner	Art Unit	
	Laura Edwards	1792	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-45* is/are pending in the application.

4a) Of the above claim(s) *25-33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,8-24 and 34-45* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20080319*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 21 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by XP-000980708.

XP provides a system for coating an implantable medical device with a coating composition, comprising a reservoir or cup (E) holding a coating composition (i.e., polymer and therapeutic agent) and including a hollowed tubular textile/cloth/fiber/filament type liner body; an applicator including a planar or flat sheet (C, D) including a coating surface and a porous region in fluid communication with the coating composition in the reservoir, wherein the porous region is capable of conveying the coating composition from the reservoir to the coating surface via wicking/capillary action; and a rotatable support element or mandrel (A) to support an implantable medical device in close proximity to or in contact with the coating surface of the applicator wherein the cloth liner body are configured such that when the mandrel supported medical device is inserted into the bore by user hands and rotated against the inner surface of the liner body, coating composition is applied to the medical device (see embods. of Figs. 1 and 2).

Claims 23 and 24 are rejected under 35 U.S.C. 102(e) as being anticipated by Nishi et al (US 2003/0196596) hereinafter Nishi.

Nishi provides a system for coating a luminal or inner surface of a cylindrical member with a coating composition comprising a reservoir (14) to hold a coating composition; and an applicator (21) configured for being received within a bore of the cylindrical member, the applicator including a coating surface (21a/21b) and a porous region (19) in communication with the coating composition in the reservoir, wherein the porous region is capable of loading the coating surface with the coating composition from the reservoir by wicking/capillary action; and a member (6) configured to hold the cylindrical member and allow the loading of composition on the luminal surface by the applicator while the member holds the medical device. The intended use coating a medical device including a stent and the intended use of a polymer solution with drug additive have both been given no patentable weight.

Claims 39-42 and 44 are rejected under 35 U.S.C. 102(e) as being anticipated by Shekalim et al (US 6,971,813) hereinafter Shekalim.

Shekalim provides a system for coating an implantable medical device with a coating composition, comprising an enclosed applicator defining a reservoir, the applicator including a coating portion (92) having a coating surface which can be porous as in a "tampon" (col. 2, lines 3-6), and a porous portion (97) for conveying coating composition to the coating portion, wherein the length of the coating portion (roller or tampon) is substantially greater than the length of the porous portion; and a support element (104) to support an implantable medical device (99) in close proximity to or in contact with the coating surface of the applicator.

With respect to claim 40, when the system is laid on its side in a horizontal disposition, at one of the coating surface would be above the reservoir.

With respect to claim 41, a portion of the roller (92) is pressed against the porous portion (97) such that when the system is laid on its side, the roller (92) would be at least partially in the reservoir.

With respect to claim 42, see at least one pressure arm defining a pressure device (col. 11, lines 39+).

With respect to claim 44, when the system is laid on its side in a horizontal disposition, each roller (92) would constitute a horizontally disposed cylinder.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4, 12, 13, 15, 16, 34-36, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over XP-000980708 in view of Hijlkema et al (US 6,739,033).

The teachings of XP have been mentioned above but XP is silent concerning providing a temperature controller in communication with parts of the system (at least one of applicator, support element and reservoir) so as to control the temperature (heating or cooling) of the coating material. However, it was known in the art, at the time the invention was made, to provide a temperature controller (enabling heating or cooling) in communication with parts of a stent manufacturing/coating system in order to maintain a desired temperature of the coating on stent in order to prevent degradation of the coated stent product as evidenced by Hijlkema et al (col. 3, lines 11-24; col. 5, lines 9-24; col.6, lines 31-44 and lines 60+ to col. 7, line 12). It would have been obvious to one of ordinary skill in the art to provide a temperature controller as taught by Hijlkema et al in communication with the XP system in order to maintain a desired temperature of the coating on stent to prevent degradation of the stent product.

With respect to claim 3, there is no teaching of a half tubular body configured to receive the device; however, it would have been within the level of one skilled in the art to make the applicator of half of a tubular body so as to use less material to make the coating system and thereby lower manufacturing costs.

With respect to claims 34-36, the characteristics of the applicator from including uniform pores to the applicator having filaments or capillaries goes to the characteristics of the foam or cloth. Such characteristics of the applicator would be well within the purview of one skilled in the art so as to control the amount of coating material to be applied and retained on the medical implant device.

With respect to claim 38, with the applicator being soaked or saturated with coating material, one of ordinary skill in the art would expect drainage or an excess of coating material to be retained in the bottom of the reservoir.

Claims 5, 6, 8, 9, and 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over XP-000980708 in view of Hijlkema et al (US 6,739,033) as applied to claim 1 above, and further in view of Sarada et al (US 5,136,968), hereinafter referred to Sarada.

The teachings of XP and Hijlkema have been mentioned above and while the planar sheet is used to coat the stent include foam, cloth (fibre/filament based material), etc., XP/Hijlkema fail to suggest the pore characteristic (pore radius of .1 microns to 1000 microns) of the foam or cloth. However, it was known in the coating art, at the time the invention was made to provide at least one porous applicator with a porous region in the range of less than 30 microns to provide for metering of coating material from the coating reservoir as evidenced by Sarada (col. 3, lines 12-14). In light of the teachings of Sarada, it would have been obvious to one of ordinary skill in the art to provide the system as defined by the combination above with a porous region having a pore size including a radius in the claimed range in order to allow for metering of the coating material from the reservoir. Furthermore, it would have been obvious to one of ordinary skill in the art to determine, via routine, experimentation, the appropriate pore characteristics including pore radius and degree of porosity, in accordance with the medical device being produced and the amount of coating material sought to be retained on the medical implant device.

With respect to claims 8, 9, and 18-20, the XP system provides for a foam or sponge based porous sheet but a layered sponge or foamed sheet having different porosities, is not set

forth. However, it was known in the coating art, at the time the invention was made to provide at least one porous applicator with a porous region in the range of less than 30 microns to provide for metering of coating material from the coating reservoir adjacent another porous applicator with the latter porous applicator having a greater pore dimension as evidenced by Sarada (col. 3, lines 5-14). In light of the teachings of Sarada, it would have been obvious to one of ordinary skill in the art to provide the system as defined by the combination above with two porous regions having different pore dimensions in order to provide a layered sponge or foamed sheet in order to control the wicking of the coating from the reservoir to the sheet to the medical device so as to provide a desired thickness of coating thereon.

Claims 10, 14, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over XP-000980708 in view of Hijlkema et al (US 6,739,033) as applied to claim 1 above, and further in view of Heller et al (US 2003/0215564), hereinafter referred to Heller.

The teachings of XP and Hijlkema have been mentioned above and neither teaches nor suggests an apparatus to rotate the support element and XP merely shows that the mandrel is rotated, presumably by hand. However, it was known in the art at the time the invention was made to provide a mandrel manipulative device for rotating as well as vibrating a mandrel or support element to facilitate coating of the mandrel mounted stent in the reservoir of coating composition as evidenced by Heller [0026]. It would have been obvious to one of ordinary skill in the art to provide a mandrel manipulative device as taught by Heller in communication with the mandrel or support element of the system defined by the combination above in order to

rotating as well as vibrating the stent causing pressure to transfer coating material from the porous applicator to the surface of the stent.

Claim 11 is rejected under 35 U.S.C. 103(a) as being unpatentable over XP-000980708 in view of Hijlkema et al (US 6,739,033) as applied to claim 1 above, and further in view Frisch (US 4,906,423).

The teachings of XP/Hijlkema have been mentioned but both are silent concerning the porous applicator being inserted into the bore of the medical device or stent. However, it was known in the art to manufacturing a prosthetic device or stent, to provide for a porous mandrel to process the stent as evidenced, by Frisch (col.. 3, lines 60-65; col. 4, lines 23-37). It would have been obvious to one of ordinary skill in the art to provide a porous mandrel as taught by Frisch in the system as defined by the combination above as an interior coating means within the stent to allow for the transfer of coating material so as to coat inside the stent.

Claim 37 is rejected under 35 U.S.C. 103(a) as being unpatentable over XP-000980708.

The teachings of XP have been mentioned above but XP is silent concerning characteristics of the applicator including the cloth or foam with filaments or capillaries respectively in a parallel arrangement. However, such an arrangement of filaments or capillaries in the cloth or foam, respectively, would go to characteristics of the applicator to control the amount of coating to be applied and retained on the medical device and therefore, said parallel prearrangement would be well within the purview of one skilled in the art.

Claims 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over XP-000980708 in view of Kravitz (US 4,976,615).

XP provides a system for coating an implantable medical device with a coating composition, comprising a reservoir or cup (E) holding a coating composition (i.e., polymer and therapeutic agent) and including a hollowed tubular textile/cloth/fiber/filament type liner body; an applicator including a planar or flat sheet (C, D) including a coating surface and a porous region in fluid communication with the coating composition in the reservoir, wherein the porous region is capable of conveying the coating composition from the reservoir to the coating surface via wicking/capillary action; and a rotatable support element or mandrel (A) to support an implantable medical device in close proximity to or in contact with the coating surface of the applicator wherein the cloth liner body are configured such that when the mandrel supported medical device is inserted into the bore by user hands and rotated against the inner surface of the liner body, coating composition is applied to the medical device (see embods. of Figs. 1 and 2). XP is silent concerning the length and/or width of the coating conveying portion being greater than the length and/or width of the porous portion. However, it was known in the medical art, at the time the invention was made to provide a porous body inserted into a receptacle with a length and/or width of the upper portion of the porous body being greater than the lower portion of the porous body disposed within the receptacle to support various size medical devices as evidenced by Kravitz (col. 3, lines 33-46). In light of the teachings of Kravitz, one of ordinary skill in the art would readily appreciate the provision of the coating conveying portion being greater than the length and/or width of the porous portion in order to accommodate the coating a various sized mandrels having at least one of more medical devices thereon.

Claims 42 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over XP-000980708 in view of Kravitz (US 4,976,615) as applied to claim 39 above and further in view of Heller et al ((US 2003/0215564), hereinafter referred to Heller.

The teachings of XP/Kravitz have been mentioned above and neither teaches nor suggests a pressure device to impart pressure to the mandrel or support element to wick coating material from the porous applicator. However, it was known in the art at the time the invention was made to provide a mandrel manipulative device for rotating as well as vibrating a mandrel or support element to thereby facilitate pressuring of the mandrel having the stent mounted thereon against walls of the porous applicator to coat the stent as evidenced by Heller [0026]. It would have been obvious to one of ordinary skill in the art to provide a mandrel manipulative device as taught by Heller in communication with the mandrel or support element of the system defined by the combination above in order to rotating as well as vibrating the stent causing pressure to transfer coating material from the porous applicator to the surface of the stent.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over XP-000980708 in view of Kravitz (US 4,976,615) as applied to claim 39 above and further in view of Sarada et al (US 5,136,968), hereinafter referred to Sarada.

XP/Kravitz provide a system for coating an implantable medical device with a coating composition. XP provides for foam or sponge based porous sheet but a layered sponge or foamed sheet having different porosities, is not set forth. However, it was known in the coating art, at the time the invention was made to provide at least one porous applicator with a porous region in the range of less than 30 microns to provide for metering of coating material from the

coating reservoir adjacent another porous applicator with the latter porous applicator having a greater pore dimension as evidenced by Sarada (col. 3, lines 5-14). In light of the teachings of Sarada, it would have been obvious to one of ordinary skill in the art to provide the system as defined by the combination above with two porous regions having different pore dimensions in order to provide a layered sponge or foamed sheet in order to control the wicking of the coating from the reservoir to the sheet to the medical device so as to provide a desired thickness of coating thereon.

Claim 43 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shekalim et al (US 6,971,813) hereinafter Shekalim.

Shekalim provides a system for coating an implantable medical device with a coating composition as mentioned previously. Shekalim is silent concerning a sealed space with respect to a surface of the coating portion of the applicator. However, one skilled in the art would readily appreciate sealing of a surface with foil or protective covering until desired use of the system. Therefore, it would have been obvious to one of ordinary skill in the art to provide sealing of a surface of the coating portion to minimize contamination of the system until the system is used.

Claim 45 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shekalim et al (US 6,971,813) hereinafter Shekalim in view of Sarada et al (US 5,136,968), hereinafter referred to Sarada.

Shekalim provides a system for coating an implantable medical device with a coating composition as mentioned previously. Shekalim provides for foam or sponge based porous sheet but a layered sponge or foamed sheet having different porosities, is not set forth. However, it was known in the coating art, at the time the invention was made to provide at least one porous applicator with a porous region in the range of less than 30 microns to provide for metering of coating material from the coating reservoir adjacent another porous applicator with the latter porous applicator having a greater pore dimension as evidenced by Sarada (col. 3, lines 5-14). In light of the teachings of Sarada, it would have been obvious to one of ordinary skill in the art to provide the Shekalim system with two porous regions having different pore dimensions in order to provide a layered sponge or foamed sheet in order to control the wicking of the coating from the sheet to the medical device so as to provide a desired thickness of coating thereon.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura Edwards whose telephone number is (571) 272-1227. The examiner can normally be reached on Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nadine Norton can be reached on (571) 272-1465. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Laura Edwards/
Primary Examiner
Art Unit 1792

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May 26, 2008